Part 8 #10

1-0908M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	Before the Examiner
Cesare Gianturco	R. Lewis
Serial No. 244,669	Group Art Unit 336
Filed September 14, 1988	
ENDOVASCULAR STENT AND DELIVERY SYSTEM	

DECLARATION UNDER 35 C.F.R.§1.132 OF PAUL EATON

1. I, Paul Eaton, am a Professor Emeritus of Materials Engineering at Purdue University in Lafayette, Indiana. I have a Bachelor's Degree in Mechanical Engineering and a Master's Degree in Industrial Engineering, both with special concentrations in materials engineering. Over the last 42 years I have been engaged in teaching, research and consulting in the fields of materials engineering and metallurgy, including analysis of the strength and mechanics of materials.

2. I have thoroughly reviewed two articles by Julio Palmaz entitled "Expandable Intrahepatic Portocaval Shunt Stents" and "Expandable intraluminal vascular graft: A feasibility study", a patent to Palmaz, U.S. No. 4,733,665, and a patent to Gianturco, 4,800,882. In particular, I reviewed the two Palmaz articles with respect to the design and structure of the wire mesh stents described in the articles. The articles described a stainless steel wire mesh stent in which the cross points or intersections of the wires were silver soldered. The stent was expanded uniformly radially outward by a balloon. The stent expanded to a larger uniform diameter while shortening in longitudinal length.

3. The "Expandable Intrahepatic ... Stent" article included the statement: "The ability of the stent to retain its shape after balloon expansion was based on the deformation of the wire segments between soldered points". The "Expandable intraluminal vascular graft" article contained the following statement: "The ability of the graft to oppose recoil after expansion is because the cross points of the woven mesh are soldered."

4. After studying the two Palmaz articles, it is my opinion that the stent described in those articles retained their expanded shapes by inelastic deformation of the solder joint at the intersection of the wires, rather than by inelastic deformation of the wire segments. The solder joint between the wires, and particularly a silver soldered joint, is more malleable and has a much lower tensile strength than the stainless steel wire. Thus, the weakest component of the wire mesh stent described in the Palmaz articles is the solder joint and not the wire lengths. As the balloon is expanded, the wire lengths displace without inelastic deformation, although the solder joints do deform inelastically to fix the stent in its expanded configuration.

5. If the joints were rigid or much stronger than the wire segments, the stent could not expand uniformly radially outwardly without buckling or severe distortion of the wire segments. This phenomenon was not described in either of the Palmaz articles or in the Palmaz patent. My conclusion is further supported by FIGS. 1A and 1B of the Palmaz patent showing the wire mesh stent in its contracted and expanded conditions. In the expanded condition, according to the FIG. 1B, the wire segments apparently do not undergo any bending or axial deformation.

6. In view of my analysis of the device described in the Palmaz articles, it is my opinion that the articles do not disclose controllable expansion of a radially expandable stent by application of a force in excess of the elastic limit of wire segments making up the stent. It is further my opinion that the stent described in the articles retained their expanded shape by inelastic deformation of the solder joints at the intersection of the wire segments.

7. I, Paul Eaton, further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that my statements and opinions were made with the knowledge that willful falsity and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code.

Dated: 19 May '00

Paul B. Eaton

Paul Eaton